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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,500	08/01/2001	Nobuhiko Ogura	Q65512	3311

7590 12/18/2006
SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC
2100 Pennsylvania Avenue, N.W.
Washington, DC 20037-3202

EXAMINER

RILEY, JEZIA

ART UNIT	PAPER NUMBER
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1637

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/18/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/918,500	OGURA, NOBUHIKO	
	Examiner	Art Unit	
	Jezia Riley	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,66-72,79,82,85,88,92,95,98,101,104,107,110,113,116,119,122,125,128,131,134,137,140-143,146,149,152,155,158,161,164,167,170-175,177-183 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 66-72 is/are allowed.
- 6) ☒ Claim(s) 3,79,82,85,95,101,107,113,119,125,131,137,141-143,149,155,161,167 and 171-175 is/are rejected.
- 7) ☒ Claim(s) 88,92,98,104,110,116,122,128,134,140,146,152,158,164,170 and 177-183 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Remarks

1. Applicants' arguments, filed on 10/05/06, have been approved and entered. They have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Claim Objections

2. Claims 92, 98, 104, 110, 116, 122, 128, 134, 140, 146, 152, 158, 164, 170, 178 are objected to because of the following informalities: they depend from canceled claim 89. Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3, 79, 82, 85, 95, 101, 107, 113, 119, 125, 131, 137, 141-143, 149, 155, 161, 167, 171-175 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious Choong et al. (US 6,238,909).

Choong et al. discloses a biochemical unit comprising a substrate. Where a porous media is "present on a substrate" so as to constitute an array or matrix when it either is on a surface (e.g., a top surface as in FIG. 1), or where holes are created within, and preferably, either partially or all the way through the substrate, and the porous media is formed or placed in these holes so as to constitute the array. For instance, FIG. 2 depicts a sample array of the invention (other configurations also can be employed) from the top view wherein holes are created within and all the way through the substrate and the porous media is formed inside of or placed in these holes so as to constitute the array. By "array" or "matrix" is meant an arrangement of locations (i.e., "microlocations") on the substrate. The locations can be arranged in two dimensional arrays, three dimensional arrays, or other matrix formats. The number of microlocations can range from one microlocation to a plurality of microlocations (e.g., from two to hundreds of thousands). A device thus can be designed to have as few as one microlocation (i.e., locations comprised of polyacrylamide or other porous media that can be addressed in the methods and apparatus of the invention) or as many as hundreds of thousands of microlocations present on a substrate.

Microlocations can be of any shape, and preferably, are either round, square, or rectangular. Optionally, however, the microlocations will each have a thickness of less than about 50 microns, desirably a thickness of between about 2 and about 40 microns, even more preferably a thickness of between about 15 and about 30 microns, and optimally, will be about 25 microns thick. Furthermore, desirably the microlocations in an array are each from about 0.5 microns to about 5 centimeters, with a preferred size being about 5 to about 500 microns in size, particularly from about 50 to about 400 microns, and especially from about 100 to about 200 microns. Which inherently include 10, 1000, or more holes per cm²

Thus, preferably a device of the invention comprises a plurality of microlocations, wherein the microlocations each comprise a first binding entity having known binding characteristics, and wherein the first binding entity present in one microlocation differs from the first binding entity present in other microlocations in a known and predetermined manner. Along these lines, desirably, the first binding entity is a probe, and the sample is nucleic acid.

The "substrate" itself optionally is any solid substrate that can be employed in the invention, e.g., film, glass, Si, modified silicon, ceramic, which is viewed to inherently attenuate radiation energy (as acknowledged by applicant page 55 of the instant application).

Further the devices can be employed in a method for bioconjugating binding entities. Preferably, this method is carried out in a device having one or a plurality of microlocation(s) present on a substrate, wherein the microlocation(s) comprise a first binding entity, which can be a labeled substance. (col 3-6, 11-13)

6. Claims 131, 137, 141-143, 149, 155, 161, 167, 171-173, 175 have added functions which the prior art has not analyzed; but given the above 102 rejection analysis substantiating the basic characterization of the composition of the invention being the same as the reference, these added characteristics are presumed to be inherent in the prior art composition.

As it is pointed in *In re Fitzgerald* (205 USPQ), page 594, 2nd col., 1st full paragraph, supports the shifting of the burden of proof to the applicant that the instantly claimed invention is novel and unobvious over the prior art. Since both the prior art and the instant application prepare and use biochemical analysis unit comprising a substrate made of material which attenuates radiation, and porous material comprising arrays which appeared to be identical for binding assays. The prior art therefore suggests the instant application under 35 U.S.C. § 103(a).

7. Claims 88, 177, 179, 180-183 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

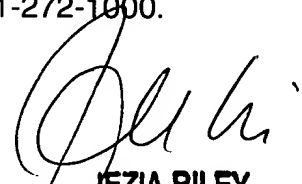
8. Claims 66-72 are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

3 December 2006



JEZIA RILEY
PRIMARY EXAMINER